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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| DICKINSON, PAUL W | |
| ART UNIT | PAPER NUMBER |
| 1618 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/829,648 | GUO, JIAN-HWA | |
| | Examiner | Art Unit | |
| | PAUL DICKINSON | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/26/2004 and 2/28/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. None of the chemical derivatives of polyol (Claim 11) or of polyoxyethylene castor oil (Claim 16) meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are, as the corresponding chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus of chemical derivatives of polyol or derivatives of polyoxyethylene castor oil encompassed by the claims, since there is no description of the structural relationship of these derivatives provided in the specification and Applicant has not provided a description as to how the base molecule may be changed while remaining a derivative.

The appearance of mere indistinct words (here the word “inhibitor”) in a specification or a claim, even an original claim, does not necessarily satisfy the written description requirement. The disclosure must allow one skilled in the art to visualize or

recognize the identity of the subject matter purportedly described. Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004). A description of what a material does, rather than of what it is, usually does not suffice to provide an adequate written description of the invention. Univ. of Cal. v. Eli Lilly, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003). No such correlation has been disclosed here; at best all that can be inferred from the instant specification is that compounds having the general formulae set forth at page 5 of the specification inhibit the production of downstream products of 14 kD PLA2, such as arachidonic acid. See the first paragraph on page 13. Whether this was specifically due to inhibition of enzyme activity, or also due inhibition of production, transcription or translation, or some combination of these, is not clear from the data presented.

The examiner recognizes that the fact situation in the Rochester cases was extreme, with Applicant disclosing there no (or possibly one) specific compounds. The reasoning provided by the court can be fairly extended to less extreme situations (*i.e.*, where a limited number of species is actually disclosed, such as here), however, given the court's recognition that:

> [I]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass.

> Accordingly, such a formula is normally an adequate description of the claimed genus. Rochester (2003) at 1431.

As was the case in Rochester, there is no such specificity here, nor could one skilled in the art identify any particular compound, other than those having the general formula set forth at the top of page 5 of the specification, as being able to inhibit any particular mechanism of 14 kDa $PLA_2$ action, other than to inhibit its "activity" in some unspecified way.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-7, 10-12, and 13-20, and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9612478 (hereafter WO '478; document provided by Applicant). WO '478 discloses sustained release nifedipine tablets comprising nifedipine (69 mg), Carbopol 974P (polyacrylic acid crosslinked with an allyl ether pentaerythritol, allyl ether of sucrose, allyl ether of propylene, or divinyl glycol) (30 mg),

dibasic sodium phosphate (75 mg), lactose (15 mg), povidone (polyvinyl pyrrolidone) (5 mg), and magnesium stearate (0.88 mg) (see Example 12). The tablet is coated with cellulose acetate butyrate (see ibid).

Claims 1-2, 4-7, 10-12, and 13-19 and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5582838 (hereafter '838). '848 discloses bilayer tablets for controlled release of nifedipine. The active layer consists of nifedipine (33 mg), Carbopol 974P (15 mg), dibasic sodium phosphate (37.5 mg), lactose (7.5 mg), povidone (2.5 mg), and magnesium stearate (0.5 mg); the inactive layer comprises Acivel PH101 (33 mg), Carbopol 974P (15 mg), sodium citrate dihydriate (37.5 mg), lactose (7.5 mg), povidone (2.5 mg) (see Example 2).

Claims 1-2, 4-7, 10-12, 13-20, and 22-26 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by WO 0245695 (hereafter WO '695; document provided by Applicant). WO '695 discloses sustained release nifedipine tablets consisting of nifedipine (60 mg), Carbopol 971P (171 mg) and 934P (9 mg), crospovidone (polyvinyl pyrrolidone), cyclodextrin (2 mg), sodium lauryl sulphate (1.5 mg), and colloidal silicon dioxoide (3 mg) (see Example 4). The tablets of the invention are coated (page 29, lines 25-29).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 13-20, and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4801460 (hereafter '460). '460 discloses controlled release solid pharmaceutical forms comprising a polymer, an active ingredient, and one or more excipients (see abstract; col 1, line 60 to col 3, line 19; Examples; Claim 1). The

polymer comprises disclosed monomers, plasticizers, and optional auxiliaries. Preferred monomers include acrylic acid, methacrylic acid, crotonic acid, maleic acid, itaconic acid, anhydrides and half esters of maleic acid and itaconic acid (col 3, lines 3-19; Examples). Vinyl acetate is an exemplified monomer (see ibid). The above monomers are present in 30%-100% by weight of the total polymer (see col 3, lines 12-19). Preferred plasticizers and auxiliaries include ethylene glycol, propylene glycol, triethylene glycol, butanediol, pentanols, hexanols, polyvinyl alchohols, and lactose (see col 2, lines 25-60; col 3, lines 38-47). The plasticizers are present in less than 20% by weight based on the total polymer and the auxiliaries are present in 0-100% by weight based on the total polymer (see col 2, lines 38-39; col 5, lines 38-40). Nifedipine is a preferred active ingredient (see col 3, line 37). The controlled release solid pharmaceutical form may be a coated sustained release tablet (see col 5, line 58 to col 6, line 2). The invention provides a simple process for the preparation of solid pharmaceutical forms with effective controlled release of active compound (see col 1, lines 60-63)

'460 fails to disclose a specific combination or example comprising nifedipine. '460 further fails to disclose the polymer component ranges disclosed in Instant Claims 10 and 13.

It would be obvious to one of ordinary skill in the art at the time the invention was made to incorporate nifedipine into the solid pharmaceutical form, with a reasonable expectation of success, as the reference teaches this as one embodiment that provides a simple process for the preparation of solid pharmaceutical forms with effective

controlled release of active compound. It would be further obvious to find the polymer component ranges disclosed in Instant Claims 10 and 13 through routine experimentation, as these are narrower ranges within the broader ranges taught by '460. See MPEP § 2144.05, II.

Claims 1-2, 4-7, 10-11, and 13-26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9612478 (hereafter WO '478; document provided by Applicant). The relevant portions of WO '478 are provided above in the rejection of Claims 1-2, 4-7, 10-12, and 13-20, and 22-26 under 35 U.S.C. 102(b). In addition, the reference teaches coating the formulation with cellulose acetate (see page 15, line 2). The disclosed formulations provide a means for the controlled *in situ* production of a dispersion of the drug, and effective release the drug (see page 5, lines 21-23).

WO '478 fails to disclose a specific combination or example of a sustained release nifedipine tablets wherein the coating is cellulose acetate.

It would be obvious to one or ordinary skill in the art at the time the invention was made to choose cellulose acetate as the coating material, with a reasonable expectation of success, as this is one embodiment taught by WO '478 that provides a means for the controlled *in situ* production of a dispersion of the drug, and effective release the drug

## ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

May 24, 2008